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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/598,215 | 08/21/2006 | Dilip K. Nakhasi | 0803-0111.03 | 1259 |

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COOK ALEX LTD
SUITE 2850
200 WEST ADAMS STREET
CHICAGO, IL 60606

| EXAMINER | |
|---|---|
| GWARTNEY, ELIZABETH A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1781 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,215 | NAKHASI ET AL. | |
| | Examiner | Art Unit | |
| | ELIZABETH GWARTNEY | 1781 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

5)☒ Claim(s) *1-39* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *1,6-14,16 and 18* is/are allowed.

7)☒ Claim(s) *2-5,15,17 and 19-39* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20110503; 20110503*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on July 30, 2010 has been entered.

2. The rejection of claims 1-39 under 35 U.S.C. 103(a) as being unpatentable over Aoyama (US 6,827,963) in view of Ester et al. (US 6,589,588) and St-Onge et al. ("Photosterols and Human Lipid Metabolism: Efficacy, Safety and Novel Foods") has been withdrawn in light of Applicants remarks filed July 30. 2010.

**3. Claims 1-39 are pending.**

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

**6. Claims 2-5, 15, 17, 19-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Regarding **claims 2 and 29**, the recitation "A composition for decreasing atherogenic risk in individuals comprising the lipid composition of claim 1, and said lipid composition, when ingested by a hypercholesterolemic individual, reduces the LDL cholesterol level of said individual by at least about 10 [15] percent" renders the claims indefinite. It is not clear if the "composition for decreasing atherogenic risk" is the same or different than the lipid composition of claim 1.

Regarding **claim 2**, the recitation "said lipid composition, when ingested by a hypercholesterolemic individual, reduces the LDL cholesterol level of said individual by at least about 10%" renders the claim indefinite. It is not clear under what circumstances the composition would display the property of reducing the LDL cholesterol of an ingesting hypercholesterolemic individual by at least 10%. In other words, while the recitation is directed to a property of the composition, it is not clear how much of the composition would have to be ingested in order for the particular property to be displayed. Further, it is not clear for how long the composition would have to be consumed at a particular dose for the property of reducing LDL cholesterol to be displayed.

Regarding **claims 3-5, 23-25 and 30-33**, the recitation directed to particular health benefits of the lipid composition render the claims indefinite. While the recitations are directed to properties of the lipid composition, it is not clear what the dose would be required in order for the particular properties to be displayed.

Regarding **claims 15 and 37**, the recitation "wherein said lipid composition is administered to the individual at a level of between about 0.4 grams and about 2 grams of said composition per kilogram of body weight per day" renders the claim indefinite. Given claim 15

is directed to a composition, it is unclear why a method step is positively recited, i.e. "is administered to the individual."

Regarding **claims 17 and 38**, the recitation "wherein said lipid composition has sensory attributes which are not significantly different from, or are significantly superior to, corresponding sensory properties of canola oil and/or of olive oil" renders the claims indefinite. It is not clear what sensory properties are similar or superior, i.e. body, oiliness, rancidity, sweet taste. Further, for any given sensory attribute, it is not clear under what conditions the lipid composition would be significantly different, i.e. when used in a food, when smelled or tasted alone, when evaluated by consumers, when evaluated by a trained sensory panel.

Regarding **claim 19**, the recitation "which is consumable by an individual and which reduces atherogenic risk for said individual" renders the claim indefinite. While the recitation is directed to a property of the lipid composition, it is unclear if the lipid composition reduces atherogenic risk in and individual when ingested or "used" by some other method. Further it is not clear what dose would be required in order for the lipid composition to reduce atherogenic risk for an individual.

Regarding **claim 22**, the recitation "[a] method for using the lipid composition of claim 1, comprising decreasing the atherogenic risk in an individual by administering the lipid composition to said individual in order to promote the health and nutrition of said individual including reducing adipose mass of said individual," renders the claim indefinite. It is unclear what steps are required for the method. Does the method for using comprise administering the lipid composition to an individual in order to promote the health and nutrition of said individual

including decreasing their atherogenic risk by reducing their adipose mass? Clarification is requested.

**Claims 2-5, 15 and 29 are rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.**

Regarding claim 2, the limitation "comprising the lipid composition of claim 1" does not further limit the subject matter of claim 1. Given the composition of claim 2 only requires the composition of claim 1, claim 2 does not further limit claim 1.

**Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.**

***Allowable Subject Matter***

7. Claims 1-39 are allowed over the prior art.

The following is a statement of reasons for the indication of allowable subject matter: Aoyama, the closest prior art of record, discloses a an oil composition for reducing lipids in blood comprising a synthesized triglyceride wherein a medium chain fatty acid having 8 to 10 carbons atoms is combined at the second carbon of the triglyceride (Abstract, C4/L40-51). Specifically, Aoyama discloses synthesized triglyceride made by mixing 40% trioleilin with 60%

caplytric acid (C10/Example 3), 40% sunflower oil rich in oleic acid with 60% caprylic acid (C8/Example 2), or 50% tricarylin with 50% oleic acid (C8/Example 1).

Aoyama discloses directed interesterification to prepare the triglycerides. Aoyama does not disclose triglycerides prepared by random interesterification. Rather, Aoyama teaches triglycerides of specific structure, i.e. Formulas I-VI. While Aoyama discloses chemical synthesis, Aoyama provides no information on the chemical esterification conditions. Thus, given Aoyama disclose triglycerides of a specific structures, since Aoyama does not specifically discloses esterification driven by chemical synthesis would result in randomization, as presently claimed, Aoyama does not disclose a catalyst interesterified randomization product.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH GWARTNEY/
Primary Examiner, Art Unit 1781